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DADE BEHRING

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April 08, 2005

Division of Dockets Management
5630 Fisher Lane, Room 1061
Rockville, MD 20852

Re: FDA Docket 2004N-0527: Medical Devices; Medical Device Reporting; Companion to Direct Final Rule

Dade Behring Inc, a manufacturer of in vitro diagnostic devices, respectfully submits comments to the proposed rule: Medical Devices; Medical Device Reporting; Companion to Direct Final rule. The availability of the guidance document was announced in the Federal Register Volume 70, Number 38, February 28, 2005.

Dade Behring appreciates FDA's efforts to revise the regulation into plain language, to ensure that guidance is clear and easy to read. We support this Direct Final Rule for the following reasons:

- It does not change the established regulatory requirement described in CFR 21 Part 803, it effectively describe the requirement in plain English.
- The proposed organization and format makes the document clear and easy to follow.
- These changes have made the regulation user friendly to all levels of the US population since they are written in an FAQ format.

Dade Behring appreciates this opportunity to provide comments and we look forward to this proposed rule in its final form.

If you have questions, please do not hesitate to contact me at 302-631-7446 or by email: norrisro@dadebehring.com

Sincerely

Robin Norris

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